

CLAIMS

1. A self-microemulsifying composition comprising Etoposide encapsulated in a pharmaceutically acceptable capsule shell.
2. The composition according to claim 1, comprising (i) a drug phase comprising Etoposide, and a solvent; (ii) a co-solvent and (iii) an emulsifying base comprising a lipid, a surfactant and a stabilizer.
3. The composition according to claim 1, comprising (i) a drug phase comprising Etoposide and a solvent selected from the group consisting of 1-methyl-2-pyrrolidone, N-methyl-pyrrolidone, dimethyl isosorbide and dimethyl sulfoxide or a mixture thereof, (ii) cosolvent selected from the group consisting of Diethyleneglycol-monoethylether, and Glycofurol or a mixture thereof and (iii) emulsifying base with a HLB value ranging between 10.0 and 20.0 comprising a lipid, surfactant, and stabilizer.
4. The composition according to claim 2, wherein Etoposide is in the range of from 1% to 20% weight/weight of the composition, the solvent is in the range of from 8% to 15% weight/weight of the composition, the Co-solvent is in the range of from 5% to 25% weight/weight of the composition and (iii) the amount of the emulsifying base is in the range from 40% to 86% weight, with respect to the total weight of the composition.
5. The composition according to claim 3, wherein Etoposide is in the range of from 1% to 20% weight/weight of the composition, the solvent is in the range of from 8% to 15% weight/weight of the composition, the Co-solvent is in the range of from 5% to 25% weight/weight of the composition and (iii) the amount of the emulsifying base is in the range from 40% to 86% weight, with respect to the total weight of the composition.
6. The composition according to claim 2, wherein the solvent is 1-methyl-2-pyrrolidine.

7. The composition according to claim 3, wherein the solvent is 1-methyl-2-pyrrolidine.
8. The composition according to claim 2, wherein the co-solvent is diethyleneglycol-mono-ethylether.
9. The composition according to claim 3, wherein the co-solvent is diethyleneglycol-mono-ethylether.
11. The composition according to claim 2, comprising (i) a drug phase comprising Etoposide and a solvent selected from N-methyl-pyrrolidone, or Dimethylisobutylacetate, (ii) cosolvent selected from Diethyleneglycol-monoethylether, and Glycofurol and (iii) emulsifying phase comprising a lipid(s) selected from the group consisting of Lauroyl macrogol-32-glycerides, Linoleoyl macrogol-6-glycerides, Caprylocaproyl macrogol-7 glycerides, Medium chain triglyceride oils, propylene glycol caprylate/caprate, propylene glycol derivatives of fatty acids, glyceryl esters of fatty acids, glycerol esters of fatty acids, and Fish lipid oils or a combination thereof; surfactant(s) selected from the group of Polysorbates, Sorbitan esters, polyethylene-propyleneglycol-copolymers, Polyoxyethylene castor oil derivatives, Caprylocaproyl Macrogol-8 glycerides, Propylene glycol laureate, Polyglyceryl-6-dioleate, Propylene glycol monocaprylates, Sodium lauryl sulphate, Docussate sodium, or bile salts or a combination thereof; and stabilizer(s) selected from the group consisting of antioxidants, carboxylic acids, and chelating agents or a combination thereof.
12. The composition of Etoposide according to claim 2 comprising Etoposide, N-methyl-pyrrolidone, Diethyleneglycolmonoethylether, medium chain triglyceride oils, Caprylocaproyl macrogol-7 glycerides and Lauroyl macrogol-32-glycerides, Polysorbates, Sorbitan esters, polyethylene-propyleneglycol-copolymers, Polyoxyethylene castor oil derivatives, Caprylocaproyl Macrogol-8 glycerides, Propylene glycol laureate, Polyglyceryl-6-dioleate, Propyleneglycol monocaprylates, propylene glycol derivatives of fatty acids, and glyceryl esters

of fatty acids, Citric acid and Vitamin-E, and encapsulated in a pharmaceutically acceptable shell.

12. The composition according to claim 2 comprising etoposide, N-methylpyrrolidone, diethyleneglycol monoethyl ether, polyoxyl 35 Castor oil, polysorbate-20, citric acid and d-alpha tocopherol.
13. The self-microemulsifying composition according to claim 2, encapsulated in a pharmaceutically acceptable shell.